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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,919	04/14/2004	James J. Modliszewski	60306-USA	7365
7590	09/06/2007			
Paul A. Fair Patent Administration FMC Corporation 1735 Market Street Philadelphia, PA 19103			EXAMINER SASAN, ARADHANA	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 09/06/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/824,919	Applicant(s) MODLISZEWSKI ET AL.	
	Examiner Aradhana Sasan	Art Unit 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 23-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22, 29-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :7/26/04, 9/20/04, 11/8/04, 8/15/05, 11/14/05, 1/9/06, 7/25/07.

## **DETAILED ACTION**

### ***Status of Application***

1. Applicant's election without traverse of Group I (claims 1-22 and 29-38) in the reply filed on 7/25/07 is acknowledged.
2. Claims 23-28 are withdrawn from consideration.
3. Claims 1-22 and 29-38 are included in the prosecution.

### ***Information Disclosure Statement***

4. The information disclosure statements (IDS) submitted on 7/26/04, 9/20/04, 11/8/04, 8/15/05, 11/14/05, 1/9/06, and 7/25/07 were filed. The submissions are in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statements.

See attached copy of PTO-1449.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17, which is dependent on claim 1, recites the limitation "said polyvalent cation" in the second last line of the claim. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-22, 29-34, and 36-38, are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilleland et al. (US 6,375,981) in view of Colegrove (US 6,509,311).

The claimed invention is a homogenous, thermoreversible gel film comprising a film-forming amount of a water soluble, thermoreversible alginate and optionally at least one of a plasticizer, a second film former, bulking agent, and a pH controlling agent.

Gilleland teaches soft gel film forming compositions comprising starch, gum, and plasticizer and can be used as a gelatin replacement (Col. 1, lines 51-59). A "soft gel capsule that comprises a sealed capsule wall and a first substance that is encapsulated by the capsule wall" is disclosed (Col. 2, lines 25-29). The film or capsule wall consists essentially of the combination of starch material, gum, and plasticizer (Col. 2, lines 30-33). The film-forming composition preferably comprises "25-75% starch material, 25-75% plasticizer, and 0.1-15% gum" (Col. 1, lines 62-68). The starch material is disclosed as chemically modified starch such as derivatives (ether and ester) of starch (Col. 2, lines 1-9). The gum is selected from alginates, carrageenan, locust bean, xanthan, gellan, agar, guar, gum arabic and pectin (Col. 2, lines 13-15). The plasticizer comprises at least one polyol such as glycerol, sorbitol, and maltitol (Col. 2, lines 17-20). Monovalent or divalent cations such as calcium are disclosed as optional

ingredients for the composition (Col. 2, lines 20-23). Substances that can be encapsulated by the capsule wall include drugs, vitamins, and nutritional supplements (Col. 2, lines 36-38). Additives such as flavorings agents are also disclosed (Col. 4, lines 51-54). Thermo-reversibility of the films was assessed (Col. 6, lines 15-18 and Table 1) along with tensile strength measurements (Col. 6, lines 33-34). It is disclosed that "edible films are prepared by blending together the starch, gum, plasticizer, and water, and heating the mixture to a temperature and for a time sufficient to gelatinize the starch fully ..." (Col. 3, lines 3-6). Also, suitable additives that may be incorporated into the composition without any adverse effects on the properties exhibited by the composition include flavoring agents (Col. 4, lines 49-56).

Gilleland does not expressly teach propylene glycol alginates.

Colegrove teaches propylene glycol alginate gels (Col. 1, lines 20-26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the composition comprising alginate as the gum, starch, and plasticizer for soft gel films and gelatin replacement capsules and assess the thermo-reversibility of the films, as suggested by Gilleland, and combine it with the propylene glycol alginates, as suggested by Colegrove, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Day teaches advantages of the thermoreversible alginate (use in calcium containing products, resistance to degradation, and stability).

Regarding instant claim 1, the limitation of the homogenous thermoreversible gel film would have been obvious to one skilled in the art over the film forming composition taught by Gilleland because the film forming composition taught by Gilleland can be used to form capsules. One skilled in the art would know that the film-forming and encapsulating material would have to be uniform or homogenous to avoid films and capsules that have lumps of unmixed components which leads to brittleness and instability. The thermoreversible alginate would have been obvious to one skilled in the art over the thermoreversible film formulation taught by Gilleland. The film-forming amount of the alginate would have been obvious over the percentage of gum in the film-forming composition taught by Gilleland. The plasticizer would have been obvious over the plasticizers glycerol, sorbitol, and maltitol taught by Gilleland. The second film former and bulking agent would have been obvious over the starch taught by Gilleland. The pH controlling agent would be a component that one skilled in the art would use in the composition in order to optimize the gel film strength and stability during the process of routine experimentation.

Regarding instant claims 2 and 5, the limitation of the second film former would have been obvious to one skilled in the art over the starch derivatives, carrageenan, gums, and pectin taught by Gilleland.

Regarding instant claims 3-4, the limitation of the various alginates would have been obvious to one skilled in the art over the teaching of alginates by Gilleland. Further, one skilled in the art would use the various commercially available alginates

such as propylene glycol alginate for gel film formation as suggested by Colegrove (Col. 1, lines 20-26).

Regarding instant claim 6, the limitation of the amount of alginate being at least 10% of the film formers would have been obvious to one skilled in the art over the 0.1-15% gum in the gel film formulation taught by Gilleland.

Regarding instant claim 7, the limitation of the alginate would have been obvious to one skilled in the art over the alginates taught by Gilleland and the propylene glycol alginate taught by Colegrove. The starch derivatives, sorbitol, and glycerin would have been obvious over the starch derivatives, sorbitol, and glycerol taught by Gilleland.

Regarding instant claims 8-11, the limitation of the break force of the film would have been obvious to one skilled in the art over the alginate based gel film and tensile strength measurement taught by Gilleland because one skilled in the art would use texture analyzers to test the strength of the gel films during routine optimization. The recited break force figures are obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claims 12-16, the limitation of solids content of the gel film would have been obvious to one skilled in the art over the teaching by Gilleland that the solids concentration in the composition will be about 30-70% by weight (Col. 1, lines 60-61). One with ordinary skill in the art would vary the solids content in the gel film composition during the process of routine experimentation in order to optimize the film stability and capsule formation. The limitations of solids content greater than 70%



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(instant claims 15 and 16) are obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claim 17, the limitation of the plasticizer would have been obvious to one skilled in the art over the plasticizers glycerol, sorbitol, and maltitol taught by Gilleland. The second film former and bulking agent would have been obvious over the starch and starch derivatives taught by Gilleland. The polyvalent cation limitation would have been obvious over the cations (such as calcium) disclosed by Gilleland.

Regarding instant claim 18, the limitation of alginate being the only film former in the gel film would have been obvious to one skilled in the art over the propylene glycol alginate gels taught by Colegrove (Col. 2, examples 1-6, lines 25-67).

Regarding instant claim 19, the limitation of the second film former would have been obvious to one skilled in the art over the carrageenan taught by Gilleland.

Regarding instant claims 20, 34, and 38, the limitation of soft capsules comprising the film would have been obvious to one skilled in the art over the soft gel capsule (produced from the film forming composition) comprising a sealed capsule wall and an encapsulated substance taught by Gilleland.

Regarding instant claim 21, the limitation of the capsule shell having a solids content of at least 50% would have been obvious over the soft gel capsules taught by Gilleland because one skilled in the art would modify the solids content of the film forming composition in order to optimize capsule shell formation, capsule sealing, and capsule stability.

Regarding instant claim 22, 34, and 38, the limitation of the encapsulated substance would have been obvious to one skilled in the art over the drugs, vitamins, and nutritional supplements that can be encapsulated by the capsule wall, as taught by Gilleland.

Regarding instant claims 29-31, the limitations of a solid form encapsulated by the gel film, a fill material, and a hard capsule, would have been obvious to one skilled in the art over the capsule wall (produced from the film forming composition) that encapsulates "any variety of materials which have been encapsulated by gelatin in the past", as taught by Gilleland (Col. 2, lines 34-36). One skilled in the art would know that the recited fill materials (powder, tablet, caplet, microcapsule or capsule) are readily encapsulated by gelatin capsules (hard capsules and soft capsules) and can be encapsulated by the capsule (produced from the film forming composition) as taught by Gilleland.

Regarding instant claims 32-33, the limitation of having a polyvalent cation level of 5% or less and 2% or less would have been obvious to one skilled in the art over the optional inclusion of cations in the film forming composition taught by Gilleland. One skilled in the art would minimize the amount of cations, as they are known in the art to cross link with alginates.

Regarding instant claims 36-37, the limitation of the gel film containing the alginate, flavorant and water would have been obvious to one skilled in the art over the Gilleland teaching that edible films are prepared by blending the starch, gum, plasticizer, and water. The limitation of flavorant as corn syrup would have been obvious

over the Gilleland teaching that additives such as flavoring agents can be used in the composition. One skilled in the art would know that corn syrup is a readily available flavoring agent and would use it as an additive in the composition.

9. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilleland et al. (US 6,375,981) in view of Cade et al. (US 6,517,865).

The teaching of Gilleland is stated above.

Gilleland does not expressly teach a composition without a plasticizer.

Cade teaches polymer film compositions for hard and soft capsules comprising water-soluble cellulose ethers, hydrocolloids and sequestering agents (Abstract). Cellulose ethers such as alkyl celluloses are disclosed (Col. 1, line 66 to Col. 2, line 4). Hydrocolloids such as gellan, alginates, carrageenan, pectin, starch, pullulan, and dextran are disclosed along with the amount of gum being between 0.01 to 2% (Col. 2, lines 10-29). Sequestering can be adjusted by the addition of monovalent or divalent cations such as  $\text{Ca}^{++}$  or  $\text{Mg}^{++}$  (Col. 2, lines 38-40). The plasticizers disclosed include polyethylene glycol, glycerol, and sorbitol, with amounts ranging from 0 to 40% (Col. 2, lines 55-62). The examples include compositions 1-4, which do not include plasticizer (Col. 3, lines 46-56).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the film forming thermoreversible composition comprising alginate as the gum, as suggested by Gilleland, and combine it with the film composition without plasticizer, as suggested by Cade, and produce the instant invention.

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One of ordinary skill in the art would have been motivated to do this because Cade teaches that plasticizer can be at 0% in the composition and capsules made with the composition "have a non-animal polymer composition, an improved dissolution behavior, an enhanced elasticity and show higher transparency" (Col. 2, lines 46-48).

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1, 2, 8-11, 17, 22, and 35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 10-15, 23-25 of copending Application No. 10/824,957 ('957 hereinafter).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a homogenous,

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thermoreversible gel film comprising a film-forming amount of a water-soluble, thermoreversible alginate and optionally at least one of a plasticizer, a second film former, bulking agent, and a pH controlling agent. Claims of '957 are also drawn to a delivery system comprising a homogenous, thermoreversible gel film that comprises a film-forming amount of a water soluble, thermoreversible alginate and optionally at least one of a plasticizer, a second film former, bulking agent, a pH controlling agent, and an active substance. The difference between the claims is that the claims of '957 include the limitation of an active substance. However, instant claims also include encapsulated substances selected from pharmaceuticals, vitamins, nutritional supplements etc. Therefore, it would have been obvious to one skilled in the art to include an active ingredient for encapsulation by the thermoreversible gel film. Since the instant application claims encapsulated substances by thermoreversible gel films, it is obvious over the claims of '957 and thus they are not patentably distinct over each other.


This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

12. No claims are allowed.
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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